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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,665	11/13/2001	Kaia Palm	CEMINES.002A	8494
24113	7590	09/15/2005	EXAMINER	
PATTERSON, THUENTE, SKAAR & CHRISTENSEN, P.A. 4800 IDS CENTER 80 SOUTH 8TH STREET MINNEAPOLIS, MN 55402-2100			UNGAR, SUSAN NMN	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 09/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/992,665	PALM, KAIA	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 05 July 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 67-134 is/are pending in the application.
- 4a) Of the above claim(s) 74, 82-95 and 97-134 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 67-73, 75-81 and 96 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/15/05</u> | 6) <input type="checkbox"/> Other: _____ |

1. The Amendment filed July 5, 2005 in response to the Office Action of March 1, 2005 is acknowledged and has been entered. Previously pending claims 1-66 have been cancelled, claims 67, 71, 73, 75, 77-80 and 96 have been amended. Claims 67-73, 75-81, 96 are currently being examined. It is noted that given the prior art set forth below, Examiner is withdrawing the restriction requirement as it is drawn to the limitations of claim 75 as drawn to lung cancer, small cell lung cancer and non small cell lung cancer and is rejoining claims drawn only to those limitations to the instantly examined invention.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The following rejections are being maintained:

Claim Rejections - 35 USC § 112

4. Claims 67-73, 75-81 and 96 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the Paper mailed March 1, 2005, Section 6, pages 5-7.

Applicant argues that there is no limitation in the claim to only Hey/HRT proteins and therefore the Office Action's limitation of the claimed invention to only Hey/HRT proteins is incorrect. When the claimed invention is considered as a whole, the interpretation of the claim as allowing testing only for Hey/HRT is manifestly contrary to reason because the specification clearly teaches testing a variety of transcription factors, with the Hey/HRT family being only one such factor.

The argument has been considered but has not been found persuasive because although claim 67 is clearly not limited to only Hey/HRT proteins, the claimed inventions are not considered as a whole, but rather the invention is

considered in light of Applicant's election filed December 10, 2004. Applicant has elected the Invention of Group 37, which includes Group A/Claim 82 (which for the reasons of record has been withdrawn from consideration) and Group (d) which required the election of a single specific factor or a specific combination of the 43 specific factors recited in claim 96 (see page 20 of the Paper mailed September 10, 2004). Since Applicant elected the Hey/HRT family of proteins, those are the specifically elected combination of factors that will be examined if the generic claim is not found to be allowable. Given that the claims drawn to Hey/HRT family of proteins are not enabled, for the reasons of record, the generic claim is also not enabled and therefore is not allowable.

Applicant further argues that restriction practice calls for a search of transcription factors that include at least one Hey/HRT family protein wherein the factors are involved in testing a sample obtained from the host for an autoimmune response against the plurality of transcription factors and that in the absence of prior art involving Hey/HRT, other transcription factors that are involved in the claimed testing would then be searched. The argument has been considered but has not been found persuasive because the claims have been examined for at least one Hey/HRT family protein and in fact were examined for multiple Hey/HRT family proteins and were not found to be enabled. Although Applicant argues that in the absence of prior art involving Hey/HRT proteins that other transcription factors should be searched, this is in fact not the case. Given that the claims drawn to Hey/HRT family of proteins are not enabled, for the reasons of record, the generic claim is also not enabled and therefore is not allowable and no additional transcription factors will be searched. Applicant is directed to the Paper mailed

September 10, 2004, Section 5, page 17 and to MPEP 804.01 for further information on linking claim restriction practice.

5. Claim 80 remains rejected under 35 USC 112, first paragraph for the reasons previously set forth in the Paper mailed March 1, 2005, Section 9, pages 7-8.

The rejection of claim 80 under 35 CFR 112, first paragraph is maintained because applicant did not distinctly and specifically point out the supposed errors in the rejection.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

6. Claims 67-73, 76-81 are rejected under 35 USC 102(b) as being anticipated by Mudenda et al (Br. J. Cancer, 1994, 69:1115-1119).

It is noted that, given that the specification does not define the term “plurality”, it is assumed for examination purposes that a plurality of transcription factors means more than one transcription factor but does not mean that the transcription factors are different factors. Thus, for example, an autoimmune response against one hundred p53 antigens is a response against a plurality of transcription factors.

It is noted that since the specification does not define the term “peptide”, it is assumed for examination purposes that the term “peptide” is meant to have the meaning conventional in the art that is “Two or more amino acids joined by a bond called a “peptide bond,”. Thus, any polypeptide of two or more amino acids is considered to be a “peptide”.

It is noted that since the specification does not define the term “array”, it is assumed for examination purposes that the term “array” is meant to have the

meaning conventional in the art that is “A series of variables (or objects) that are of the same type and size” Thus, any series of objects that are the same type and size, for example a series of p53 antigens is considered an array.

The claims are drawn to a method of testing a host for a cancer, the method comprising testing a sample obtained from the host for an autoimmune response against a plurality of transcription factors, wherein the detection of an autoimmune response against said transcription factors is indicative that the host has a cancer and further indicates a type of the cancer (claim 67), wherein the sample is a tissue or a bodily fluid (claim 68), serum (claim 69), wherein testing the sample comprises using the sample for an autoantibody against the plurality of transcription factors (claim 70), wherein the at least one transcription factor is immobilized (claim 71), wherein the testing comprises an ELISA (claim 72), wherein the cancer is a presence of a cancer cell in a host (claim 73), wherein the sample comprises an NK cell, a ZT cell, a lymphocytes (claim 76), wherein testing comprises detecting antibodies against the plurality of transcription factors (claim 77), using the plurality of transcription factors to detect the antibodies (claim 78), using an array of peptides to detect the antibodies (claim 79), wherein at least four antibodies against the transcription factors are detected (claim 80), wherein the host is human (claim 81).

Mudenda et al teach a method of testing a host for a cancer, aggressive breast cancer (see abstract), the method comprising testing a serum sample obtained from the host for an autoimmune response against a plurality of transcription factors, p53 proteins wherein the detection of an autoimmune response against said transcription factors is indicative that the host has a cancer and further indicates a type of the cancer, aggressive breast cancer (see abstract),

wherein testing the sample comprises using the sample for an autoantibody against the plurality of transcription factors, wherein the p53 proteins are immobilized and the assay is an ELISA see page 116, cols 1 and 2) wherein the cancer is a presence of a cancer cell in a human host, that is 182 newly diagnosed breast cancer patients, wherein since the sample is a serum sample, the sample inherently comprises an NK cell, a ZT cell, and a lymphocytes, wherein testing comprises detecting antibodies against the plurality of transcription factors, using the plurality of transcription factors to detect the antibodies, using an array of peptides to detect the antibodies, wherein at least four antibodies against the transcription factors are detected (see the abstract). All of the limitations of the claims are met.

7. Claims 67, 73 and 75 are rejected under 35 USC 102(b) as being anticipated by Winter et al (Cancer Research, 1992, 52:4168-4174)

It is noted that, given that the specification does not define the term “plurality”, it is assumed for examination purposes that a plurality of transcription factors means more than one transcription factor but does not mean that the transcription factors are different factors. Thus, for example, an autoimmune response against 100 p53 antigens is a response against a plurality of transcription factors.

The claims are drawn to a method of testing a host for a cancer, the method comprising testing a sample obtained from the host for an autoimmune response against a plurality of transcription factors, wherein the detection of an autoimmune response against said transcription factors is indicative that the host has a cancer and further indicates a type of the cancer (claim 67), wherein the cancer is a presence of a cancer cell in the host (claim 73), wherein the cancer cell is a lung cancer cell, SCLC, NSCLC cell (claim 75).

Winter et al teach method of testing a host for a lung cancer, SCLC, NSCLC patients with a missense p53 mutation (see abstract), the method comprising testing a sample, serum, obtained from the host for an autoimmune response against a plurality of transcription factors, p53 proteins, wherein the detection of an autoimmune response against said transcription factors is indicative that the host has a cancer and further indicates a type of the cancer, lung cancer, NSCLC, SCLC characterized by missense p53 mutation. Wherein the cancer is a presence of a cancer cell in the host wherein the cancer cell is a lung cancer cell, SCLC, NSCLC cell wherein it was determined that 10% of the patients with SCLC tested positive for p53 autoantibodies and 33% of the patients tested for NSCLC tested positive for p53 antibodies (see abstract), all of which had p53 missense mutations. All of the limitations of the claims are met.

New Grounds of Objection

8. Claim 75 is objected to because it does not appear to further limit claim 67 from which it depends. The limitation of “wherein the cancer is a presence of a cancer cell in the host.” appears to be redundant. Appropriate correction is required.

9. All other objections and rejections recited in the previous Office Action are hereby withdrawn.

10. No claims allowed.

11. Applicant's amendment necessitated the new grounds of rejection.

Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a).

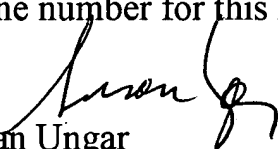
Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF

THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is 571-273-8300.


Susan Ungar
Primary Patent Examiner
September 7, 2005